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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/268,437 Filing Date: March 12, 1999 Appellant(s): DING ET AL.

GREGORY LUNN
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed September 30, 2005, appealing from the Office action mailed March 28, 2005.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct, except for the withdrawn rejection as follows.

WITHDRAWN REJECTIONS

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The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

A) Rejection of claims 1-5, 11, and 12 under 35 USC 112, second paragraph, for the recitation of the phrase "adapted to receive a sample", has been withdrawn by Examiner.

B) Rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081), has been withdrawn by Examiner.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US PATENT 6,391,558

HENKENS et al.

3-1997

US PATENT 5,063,081

COZZETTE et al.

11/1991

(9) Grounds of Rejection

The following grounds of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- A) Claims 1-5, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Henkens et al. (US 6,391,558).

Henkens et al. disclose a simultaneous electrochemical assay device (biosensor array device) comprising a cell (circuit board) for holding a sample. The device comprises a plurality of working electrodes and one or more reference or counter electrodes. Henkens et al. teach that whether in an array of working electrodes or a single working electrode, the electrochemical assay device may optionally include a common (one) reference or counter electrode, or more reference or counter electrodes. Each of the working electrodes is adjacent (linked or attached to) an analyte binding area which has an analyte binding substrate and separated from other analyte binding areas by a distance (surface area) (see column 6, lines 32-38 and Figure 14). Analyte binding substrates (bioreporter molecules) comprise of different analyte specific proteins such as antigens, antibodies, and enzymes (reductases, peroxidases, phosphatases). See column 4, line 41 to column 6, line 38 and column 19, line 58 to column 20, line 56. The plurality of working electrodes quantitatively measure enzymatic reaction product. See column 17, line 51 to column 18, line 63 and column 41, lines 31-38. The device

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does not include a means to mix the sample in the cell. Accordingly, Henkens et al. is deemed to anticipate the claimed invention.

B) Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al. (US 5,063,081).

Cozzette et al. disclose a simultaneous electrochemical assay device (amperometric base sensor) fabricated on a substantially planar silicon substrate comprising a unit cell for holding a sample. The device has a plurality of working (catalytic) electrodes with identical geometry and area, i.e. analyte binding area or biolayer, and enzyme incorporated thereto. The working electrodes quantitatively measure enzymatic reaction products (see column 3, lines 12-28, column 13, lines 22-53, column 19, lines 23-45, column 16, lines 28-42, and column 22, lines 18-36). The unit cell may be repeated in a geometric array several hundred times on a single silicon wafer. Each working electrode is surrounded by an auxiliary and counter or reference electrode. Each of the working electrodes are adjacent to permselective silane layer having immobilized thereon, the analyte binding areas which are localized on the electrode portions of the unit cell and separated from adjacent analyte binding areas by a distance (see column 25, line 35 to column 26, line 4). The working electrodes on analyte binding areas are overlain and aligned with analyte specific proteins such as antigens and antibodies (biolayer and bioactive molecules) (see column 22). Cozzette et al. specifically teach that a plurality of electrodes may be present in a biosensor for the simultaneous measurement of different analytes using electrochemical assay

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procedures (see columns 47-51, column 58, lines 38-48, column 25, and Figure 4). The device does not include a means to mix the sample in the cell. Accordingly, Cozzette et al. is deemed to anticipate the claimed invention.

(10) Response to Argument

Appellant's arguments filed September 30, 2005 have been fully considered but they are not persuasive.

A) Appellant requests that the rejection based on the Henkens reference be withdrawn because the patent has a filing date of April 2000, which is well after Appellant's effective filing date of 1998. Appellant contends that the Henkens patent has a provisional application filing date of March 18, 1997, but it is based on a CIP application; hence the disclosure would not be the same as the Henkens patent and therefore, the rejection is inappropriate based on this reference.

In response, while the disclosure of provisional ASN 60/040,949 filed on March 18, 1997, which is the provisional application upon which the Henkens patent claims the benefit of priority to, is not the same as the specification disclosed in the Henkens patent, the subject matter of electrochemical assay device and parts thereof relied upon for the purpose of rejecting the claimed invention, are described throughout the disclosure of the provisional application, especially at pages 8-11. Even if the disclosure of the Henkens patent which is a CIP application may include subject matter that is new to the disclosure of ASN 09/044, 206, but the subject matter and limitations

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relied upon in the Henkens patent to reject the instant claims is disclosed in parent application SN 09/044,206 and provisional application SN 60/040,949, then the benefit of priority is given to the patented child application for purposes of prior art rejection for the subject matter at issue. Accordingly, ASN 60/040,949 having a filing date of March 18, 1997, is deemed properly and appropriately applicable for its benefit of priority as Provisional Application for the Henkens patent for the purpose of rejection of the claimed invention.

A copy of the disclosure of Provisional ASN 60/040,949 has been attached, herewith, for Appellant's convenience.

B) Appellant argues that the instant invention claims a common reference electrode for a plurality of working electrodes; hence, the Henkens reference cannot anticipate the claimed invention as it requires and discloses a separate reference electrode for each working electrode.

Appellant's argument is not persuasive because Appellant's contention is contradictory to the teaching of Henkens et al. Specifically, at column 6, lines 33-38, Henkens et al. teach that the electrochemical assay device "need not comprise a plurality of working and reference electrodes, but may comprise a single working electrode and a single reference electrode". Henkens et al. proceeds to teach that "whether in an array or a single electrode, the biosensor may optionally include one, i.e. common, or more reference (counter) electrodes", as recited in the rejected claims.

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C) Appellant argues that Cozzette et al. does not anticipate the claimed invention because it teaches a method of forming individual assay devices on a silicon chip.

Appellant contends that Cozzette et al. do not teach a simultaneous electrochemical assay device and that it merely teaches a structure that must be modified to be further incorporated into an electrochemical assay device. According to Appellant, the actual finished state of the device taught by Cozzette can only be used to test one analyte.

In response, while Cozzette et al. disclose methods of manufacturing microfabricated sensing devices, the subject matter relied upon to reject the claimed invention appears to teach electrochemical devices used in electrochemical assay methods such as recited in the rejected claims (see discussion of Cozzette et al. supra). Contrary to Appellant's argument that the electrochemical device of Cozzette cannot test multiple analytes simultaneously, the teaching of Cozzette et al. at column 22, lines 17-35; column 58, lines 38-48 and Figure 4 appears to teach a plurality of [indicator] electrodes in the biosensor device for use in simultaneous measurement of different ionophore analytes, i.e. ionic species such as Na, K, Cl, etc., as recited in the rejected claim.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

Systel 10/20/05

Gailene R. Gabel

Conferees:

Long V. Le (SPE)

James C. Housel (SPE)